JAN 2 5 2001

CAO GROUP

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(801) 256-9287 (fax)
Tracy S. Best, Consultant for Regulatory Affairs

K003541

Preparation Date: November 15, 2000

Summary of Safety and Effectiveness for the:

Trade Name: DenLaser 800

Common Name: Diode Pulsed 810 nm

Classification Name: Laser Instrument, Surgical

Legally Marketed Predicate Devices for Substantial Equivalence:

* Opus 10 Dental Diode Laser, Manufactured by OpusDent, Inc.

* Aurora SL Diode Laser, Manufactured by Premier Laser Systems, Inc.

* Twilight Dental Diode Laser, Manufactured by BioLase Technology, Inc.

Rationale for SE: The aforementioned laser devices and the accompanying delivery devices share similar indications for use in oral surgery, similar design features including; wavelengths, beam integrity, and cooling type. Control systems such as interlock devices, (safety systems) and displays are constantly monitored for user intervention. Functional features such as; delivery power, pulse rates, and energy type are also similar to the aforementioned devices. *Also see Attachment "A"* Comparison Chart of Equivalence.

Description of Submitted Device:

The DenLaser Model 800 Laser System is an instrument for use in the application of Oral Surgery. The laser light is produced by Solid State technology. With a output power of 10 Watts using 810 nm ±20 nm infrared laser light, the indications for use are warranted. Proprietary fiber optic delivery devices are the method for delivery of laser energy. Delivery devices and replacement tips for the hand held probe are part of the package for the indicated uses.

Intended Uses of the Elite Family Lasers:

See attachment "B" for a complete listing of indicated uses.

Technological Characteristics and Substantial Equivalence:

The Opus 10 Diode Laser primary energy output source is a diode that produces infrared laser light that my be delivered to the patient or for purposes of this submission. This system has various timing features for interval, and duration. The Aiming Beam is a Visible Red Diode @ 630-680 nm wavelength.

The Aurora Laser System uses an infrared semiconductor diode as the laser light primary source energy. The Aurora Laser System delivers similar wavelength, similar power, spot sizes and pulses of equivalent duration to the purposed DenLaser 800 laser.

The Twilight Dental Diode Laser System uses a Gallium Aluminum Arsenide solid state diode to provide energy to oral soft tissues. A flexible fiberoptic handpiece delivers the laser energy. A visible light emitted from the distal end of the handpiece points to the areas for treatment. The output power and pulse rate may be adjusted to specific user requirements. The DenLaser 800 is similar to these technical characteristics.

Performance Standards

The DenLaser complies with the requirements of 21 CFR Sub Chapter J, as required by 21 CFR 1010.2

Clinical Performance Data

None

Conclusion:

The DenLaser Model 800 Laser System is substantially equivalent to other existing oral and soft tissue surgical laser systems in commercial distribution. The DenLaser is designed to meet the electrical safety requirements of IEC 601-1. The laser head is of proprietary design laser that is operated by logic circuitry. Therefore, we believe that the DenLaser 800 is substantially equivalent to its predicate devices cited above without raising any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2001

Ms. Tracy S. Best
Consultant for Regulatory Affairs
Cao Group, Inc.
627 West Sandy Parkway
Sandy, Utah 84070

Re: K003541
Trade Name: DenLaser 800
Regulatory Class: II
Product Code: GEX
Dated: November 15, 2000
Received: November 16, 2000

Dear Ms. Best:

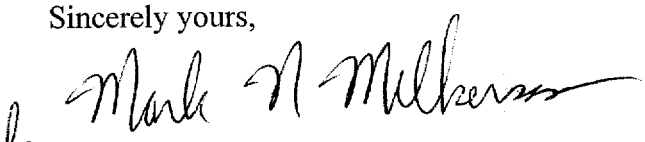
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003541

Device Name: DenLaser, Model 5800 Laser System

Indications For Use:

Dental, Oral and Soft Tissue Surgery including:

Sulcular Debridement of Diseased or Fibrous Tissue
Excision and Biopsy
Gingivectomy & Gingivoplasty
Lesion (tumor) Removal
Fibroma Removal
Tissue Retraction (Troughing)
Bacterial Decontamination
Aphthous Ulcers
Gingival Hyperplasia (Excision & Recontour)
Crown Lengthening
Operculectomy
Frenectomy
Photocoagulation

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003541

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.109)